

**From:** Vorsanger, Gary J. [JANUS]  
**To:** Moskowitz, Bruce [JANUS]  
**Sent:** 2/23/2001 1:31:26 PM  
**Subject:** RE: Abuse letter

Bruce: I was totally out of the loop on this and did not become aware of the issues until late. By that time both parties (Marketing and Med Services) were upset. It is unfortunate that Dave or Pat did not contact me directly. By the time I was involved, Marketing had written, and received permission to distribute, an abbreviated version of the Med Services document. I reviewed it late yesterday and it appeared to be a balanced presentation of the issues.

Gary

**Gary J Vorsanger, PhD., M.D.**  
Director, Medical Development  
Pain and Mycology, Medical Affairs  
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email: gvorsang@janus.jnj.com

-----Original Message-----

**From:** Moskowitz, Bruce [JANUS]  
**Sent:** Thursday, February 22, 2001 4:53 PM  
**To:** Domann, David [JANUS]; Zollo, Steve [JANUS]; Wilkinson, Patricia [JANUS]  
**Cc:** Vorsanger, Gary J. [JANUS]  
**Subject:** RE: Abuse letter

Dave: I'm going to be hung up with Sporanox issues for the coming weeks. I suggest you involve Gary for any Duragesic related issue. He's much more knowledgeable about these issues than I anyway.

**Bruce L. Moskowitz, MD**  
Group Director, Pain and Mycology, Medical Affairs  
Janssen Pharmaceutica, Inc.  
( (609) 730-3139

-----Original Message-----

**From:** Domann, David [JANUS]  
**Sent:** Wednesday, February 21, 2001 10:17 AM  
**To:** Zollo, Steve [JANUS]; Wilkinson, Patricia [JANUS]  
**Cc:** Pavia, Cheryl [JANUS]; Gorsky, Alex [JANUS]; Rasmussen, Pamela [JANUS]; Eckhardt, Jim [JANUS]; Ilobbi, Danielle [JANUS Non J&J]; Witt, James [JANUS]; Moskowitz, Bruce [JANUS]; Farup, Christina [JANUS]  
**Subject:** RE: Abuse letter

Steve:

My suggestion is that we have Pat and Bruce lead a team to review the response - I would ask that they take this on ASAP.

Just to clarify, we don't search the internet for our information - as you mentioned reports of abuse obtained from the internet would probably be very high and unmanageable. Our scope of information is limited to MEDLINE searches of the published literature.

We do have an obligation to provide a fair and balanced response to health care professionals and this is the approach we have taken all along. Again, it is very unfortunate that our competitor is operating in such an unprofessional manner.

This is a very serious issue and we understand the competitive environment in which we work. It will take a real team effort take on this issue.

Thanks.

Dave

-----Original Message-----

**From:** Zollo, Steve [JANUS]  
**Sent:** Wednesday, February 21, 2001 8:25 AM  
**To:** Domann, David [JANUS]; Wilkinson, Patricia [JANUS]; lobbi, Danielle [JANUS Non J&J]  
**Cc:** Pavia, Cheryl [JANUS]; Gorsky, Alex [JANUS]; Rasmussen, Pamela [JANUS]; Eckhardt, Jim [JANUS]; Witt, James [JANUS]; Moskowitz, Bruce [JANUS]; Farup, Christina [JANUS]  
**Subject:** RE: Abuse letter

Dave,

We are in the process of contacting Purdue about the overall promotional practices of Oxycontin vs/ Duragesic in terms of abuse. Their use of our own Professional Services letter is just the proverbial tip of the iceberg.

Let's be clear about this issue -- As the use of Duragesic continues to rise ( which it will), so will drug abusers trying to find creative ways to extract fentanyl from the patch. That's why it's a scheduled drug. As our use goes up, so will published reports of abuse. If we want to report every case in the literature, this memo will be longer than the current 7 pages. If we feel compelled to provide information about any of our products to the degree that can be found on the Internet than Dave you don't have enough people.

I would suggest we reduce this response down because frankly, the majority of physicians are asking this question in general terms and not looking specific incidences of abuse. In addition, I have requested that Jim Witt with the help of Medical Affairs review every memo on Duragesic that is being sent from Professional Services. Jim, please collaborate with Bruce on how you would like to proceed.

Dave, please get back to me on how this abuse letter is going to be modified.

Thanks,  
Steve

-----Original Message-----

**From:** Domann, David [JANUS]  
**Sent:** Wednesday, February 21, 2001 8:09 AM  
**To:** Wilkinson, Patricia [JANUS]; Zollo, Steve [JANUS]; lobbi, Danielle [JANUS Non J&J]  
**Cc:** Pavia, Cheryl [JANUS]; Gorsky, Alex [JANUS]; Rasmussen, Pamela [JANUS]; Eckhardt, Jim [JANUS]; Witt, James [JANUS]; Moskowitz, Bruce [JANUS]; Farup, Christina [JANUS]  
**Subject:** RE: Abuse letter

All:

Just a brief follow up to Pat's comments. This letter is not unlike other communications we have developed to respond to physician's inquiries related to adverse events, drug interactions, contraindications, etc., of our products. We include information in our letters and in our verbal responses to practitioners based on the available literature. If documents can be easily retrieved in a Medline literature search, we need to address them. This particular letter does contain information that demonstrates a low potential for abuse (featured early in the letter) and the few and rare instances where the transdermal system has been abused. Our responsibility is to communicate relevant information (in a fair & balanced manner) to the practitioners who prescribe our products.

Its unfortunate that another company has taken a most unprofessional approach in their encounters with physicians. Based on this unfortunate event, I agree with Pat's approach to gaining everyones feedback in reevaluating how we respond. In fact, I would suggest that Pat and Bruce Moskowitz form a group to consider our approach with this letter.

Are we giving any considerations to contacting the competitor about this practice ?

Thanks.

Dave

-----Original Message-----

**From:** Wilkinson, Patricia [JANUS]  
**Sent:** Wednesday, February 21, 2001 7:23 AM  
**To:** Zollo, Steve [JANUS]; lobbi, Danielle [JANUS Non J&J]; Domann, David [JANUS]  
**Cc:** Pavia, Cheryl [JANUS]; Gorsky, Alex [JANUS]; Rasmussen, Pamela [JANUS]; Eckhardt, Jim [JANUS]; Witt, James [JANUS]  
**Subject:** RE: Abuse letter

Everyone,

This has (basically ) been our standard letter over the last several years. Changes relatively recently made include augmentation of background on low incidence of iatrogenic addiction when opioids are used appropriately, and inclusion of reputable guidelines endorsing the use of opioids in chronic pain situations - stressing that fear of "addiction" should not deter clinicians from using opioids when indicated. Case reports have been included as they have become available in the medical literature.

We have actually discussed the level of detail regarding abuse methodology ( before the current situation with Oxycontin abuse emerged), but felt since that clinicians were specifically asking about the topic, we needed to elaborate. For perspective, please keep in mind that these articles are all in the public domain, and can be easily located on Medline by anyone with Internet access. Given that, if one of our clinicians asked a specific question, I find it difficult to justify offering less detail than the prescriber could find on Medline. In the current situation, I know we feel we need reevaluate how we're responding - this is a good thing. I welcome the group's feedback.

Thanks for asking the question

**Pat**

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-----Original Message-----

**From:** Zollo, Steve [JANUS]  
**Sent:** Tuesday, February 20, 2001 2:12 PM  
**To:** Ibbi, Danielle [JANUS Non J&J]; Domann, David [JANUS]  
**Cc:** Pavia, Cheryl [JANUS]; Wilkinson, Patricia [JANUS]; Gorsky, Alex [JANUS]; Rasmussen, Pamela [JANUS]; Eckhardt, Jim [JANUS]; Witt, James [JANUS]  
**Subject:** RE: Abuse letter

David/Pat;

Please explain to me why we have to go through such painstaking detail around every single published report on Duragesic abuse? Our problem is because of the increased scrutiny of Oxycontin abuse, physicians want to compare the relative risk Vs/ Duragesic. Our other issue is that we have gotten reports from the field that Purdue is using our own letter from Professional Services to put the abuse potential in their "perspective".

Thanks,  
Steve

-----Original Message-----

**From:** Ibbi, Danielle [JANUS Non J&J]  
**Sent:** Tuesday, February 20, 2001 9:18 AM  
**To:** Domann, David [JANUS]; Zollo, Steve [JANUS]  
**Cc:** Pavia, Cheryl [JANUS]; Wilkinson, Patricia [JANUS]  
**Subject:** Abuse letter

<< File: Dur abuse.doc >>

Sorry for the mistake in the last e-mail. This is the abuse potential letter.

Regards,

Danielle

***Danielle lobbi, PharmD***

Janssen Pharmaceutica

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